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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,317	04/13/2004	Wilfried M. Braje	ABB10043P0012US	4777

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
05/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,317	BRAJE ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-17 and 20-22* is/are allowed.

6)☒ Claim(s) *23 and 27* is/are rejected.

7)☒ Claim(s) *18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of applicants' response filed 2/15/07 and earlier response filed 10/31/06 the following applies.

The Declaration filed on 10/31/06 by Dr. Braje overcomes the how to make and use rejection for compounds now being claimed.

Applicants' response to the Request for Information is noted.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In amending the claims to read "optionally", for claim 23, a composition claim, this makes no sense since one needs at least 2 components to make a composition. It is suggested it be deleted from this claim.

Claims 18 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The following reasons apply:

1. For claim 18 and 19 more than 1 R^b substituent is permitted on the outer ring yet in claim 13 only one appears at the para position;

2. Claim 19 still embraces phenyl as "Ar" yet only pyridyl can be present in claim 13. Note proviso in the X/Y choices.

Claims 18 and 19 are objected to because of the following informalities: While "Ar" is present in main claim 1, it has been replaced by a subgeneric formula in claim 13 from which 18 and 19 depend. Thus its mention in 18 and 19 is extraneous. Appropriate correction is required.

Claim 27 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating schizophrenia and Parkinson's Disease, does not reasonably provide enablement for remaining uses inserted into the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Of the 4 references actually provided only two have been published prior to applicants' US filing date. Joyce, which published in 2001 deals with Parkinson's and schizophrenia not rejected. The second reference is by Rogoz directed to anxiety. However testing done on D3 agonists employed animal models and yet results are considered only preliminary. Note concluding sentence in Abstract- "...however, further studies are necessary to elucidate the mechanism of these actions."

Laszy and Joyce which both published in 2005 while dealing with cognitive deficits in psychotic patients emphasize the need for further evidence. In Laszy on p.568, left column, first paragraph the possibility of other neurotransmitters being responsible is discussed and thus the need for testing with selective D3 compounds as well as using other experimental models. In Joyce on p.255, left column, it is stated: "However, there is a need for additional study of the precise influence of short- and long-term-D3 receptor blockade on cognitive function. Finally, one question that could be asked is- why do the currently available antipsychotic agents with D3 receptor antagonistic properties not robustly improve the cognitive function?". Additionally, Laszy and Joyce deal with only a small portion of what constitutes "cognitive disturbances". Defects such as mental retardation, all forms of dementias (eg. Pick's Disease, multi-infarct, drug-induced), all types of learning disabilities (dyslexia, autism, etc.) and amnestic syndromes are all additional examples of what constitutes cognitive disorders for which no evidence of clinical efficacy is seen. Lastly, Heidbreder has been furnished. Again this is a later published reference directed to preliminary study implicating D3 receptors for the treatment of drug addiction. The abstract mentions the possibility of other

neurotransmitters being responsible so the need for selective D3 compounds in animal testing is warranted. The article deals with testing for such compounds in recognized animal models but there is no discussion of clinical success in man. While preliminary findings for SB-277011-A are encouraging, it has not been demonstrated that the drug is useful for all types of addiction which is covered by the claim language. As stated in MPEP 2164.05(a): "The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. > Chiron Corp. v.Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").< Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing.

Applicants have not provided any other references dealing with kidney or eating disturbances of which there are many and of varying etiology.

Thus the uses being urged are not in currently available form based on the activity relied on and the specification provides only a starting point

for further research. Note Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005 which states the following: "Patent protection is granted in return for an enabling disclsoure of an invention, not for vague intimations of general ideas that may or may not be workable.". In the same decision at p.1004 it is clearly stated that "to be enabling the specification must teach ... how to make and use the full scope of the claimed invention without undue experimentation.". This is not the case herein.

A more recent decision, Rasmusson v. SmithKline Beecham Corp. 75 USPQ 2d 1297, reiterates the level of evidentiary support needed for compliance of 35 USC 112, par.one. Note in particular last 2 paragraphs on p.1301.

The 102 rejections have been overcome by applicants' amendments to the claims, notably at Ar which requires that the rings be substituted and excludes pyrazine as a choice.

For the record applicants English translation of provisional case is **not** in the file. It is also **not** in the file of the provisional case.

A signed copy of applicants' IDS accompanies this action. Note last entry has not been considered for reason given previously.

Claims 1-17 and 20-22 are allowed.

The patents newly cited by the examiner have a similar backbone to that claimed herein but require a substituent, N-X-R1, not within applicants' scope corresponding to NR6R7 or NHR6.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E Bernhardt/

Emily Bernhardt
Primary Examiner
Art Unit 1624